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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/822,101

04/08/2004

Agostino Tucciarone

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EXAMINER

HOFFMAN, MARY C

ART UNIT

PAPER NUMBER

3733

NOTIFICATION DATE

DELIVERY MODE

02/23/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

intel_prop@arthrocare.com

Office Action Summary	Application No. 10/822,101	Applicant(s) TUCCIARONE ET AL.	
	Examiner MARY HOFFMAN	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-18 and 21-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-18 and 21-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/05/2008;12/04/2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/04/2008 has been entered.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The term "enclosed recess" is not found in the specification.

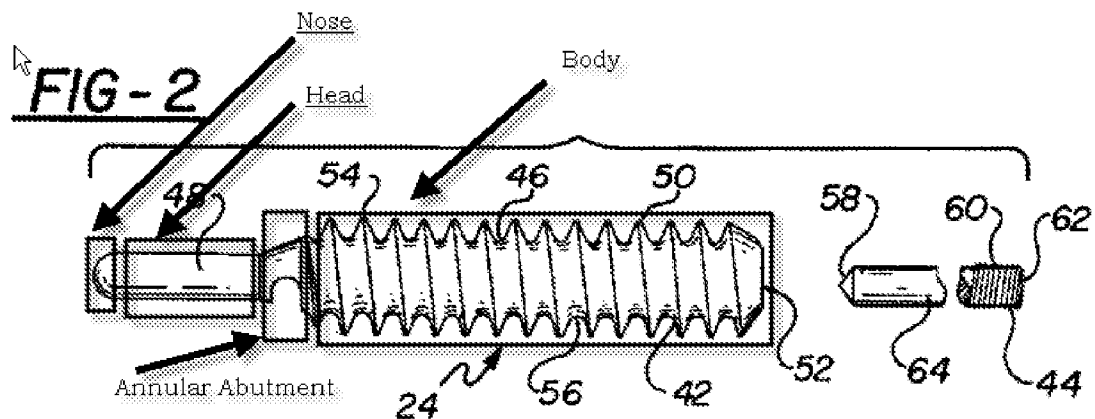
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Howell et al. (U.S. Patent No. 5,674,224) in view of Chervitz et al. (U.S. Patent No. 6,499,486).

Howell et al. disclose a method of ACL graft ligament fixation comprising the steps of providing a transverse suspension device comprising a proximal body section defining a longitudinal axis, a head section extending along the longitudinal axis and protruding distally from the body section, the head section having a smaller diameter than that of the body section, and an annular abutment surface disposed between the head section and the body section wherein the abutment surface is substantially at an angle to the longitudinal axis (FIGS. 2-3); forming a femoral tunnel and forming a transverse tunnel intersecting the femoral tunnel (FIG. 10); and the head section contacts an enclosed recess formed in an opposite wall of the femoral tunnel wherein the abutment surface urges the graft against the opposite wall (FIG. 14) to embed it. A guidewire is advanced under observation with a viewing device, specifically an arthroscope (col. 6, lines 37-53). The recess is formed with a dilator tool (ref. #124). The transverse suspension device is cannulated. The transverse tunnel is drilled to intersect and not cross the femoral tunnel. The body section comprises external threads. The device includes a nose section distal to and distinct from the head section and having a reduced diameter as compared to the head section, the nose section extending along the longitudinal axis, and an annular abutment surface distinct from the head section and disposed between the head section (see marked up figure below). The head section has a substantially constant diameter. The graft loop is compressed against the opposite wall.



Howell et al. disclose the claimed invention except for locating a graft loop in the femoral tunnel in such a manner that an open face of the loop faces an intersection where the femoral tunnel intersects the transverse tunnel and passing at least a part of the head section of the transverse suspension device through the graft loop via the transverse tunnel, the nose section being frustoconically shaped, and the abutment surface having an angle of about 90 degrees.

Chervitz et al. disclose the step of locating a graft loop in the femoral tunnel in such a manner that an open face of the loop faces an intersection where the femoral tunnel intersects the transverse tunnel and then passing at least a part of the head section of the transverse suspension device through the graft loop via the transverse tunnel as one of the numerous ways in which a graft may be positioned in the tunnel and secured (col. 1, lines 49-50).

It would have further been an obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Howell et al. with the step of locating a graft loop in the femoral tunnel in such a manner that an open face of the loop faces

Art Unit: 3733

an intersection where the femoral tunnel intersects the transverse tunnel and then passing at least a part of the head section of the transverse suspension device through the graft loop via the transverse tunnel in view of Chervitz et al. as one of the numerous ways in which a graft may be positioned in the tunnel and secured. It would have further been an obvious matter of design choice to one skilled in the art at the time the invention was made to perform the method of Howell et al. in view of Chervitz et al. with the head section being frustoconical shaped, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a head section or ligament holding nose of a transverse suspension device. *In re Dailey and Eilers*, 149 USPQ 47 (1966). It would have further been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of Howell et al. in view of Chervitz with a device having an angle of about 90 degrees, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chervitz et al. (U.S. Patent No. 6,499,486) in view of Clark et al. (U.S. Patent 6,306,138).

Chervitz et al. disclose a method of ACL graft ligament fixation comprising the steps of forming a passing pin tunnel in a femur (FIG. 10), the passing pin tunnel having a longitudinal axis and exiting a superior wall of the femur; forming a femoral tunnel

Art Unit: 3733

along the longitudinal axis, the femoral tunnel having a larger diameter than the passing pin tunnel and terminating in the femur; forming a transverse tunnel intersecting the femoral tunnel; locating a graft loop (ref. #25) in the femoral tunnel in such a manner that an open face of the loop faces an intersection where the femoral tunnel intersects the transverse tunnel, and wherein the locating comprises pulling on sutures (ref. #100) holding the graft loop to locate the graft loop, and the pulling on sutures comprises pulling on the sutures through the passing pin tunnel; passing at least a part of a head section of a transverse suspension device (see FIG. 4) through the graft loop via the transverse tunnel until the head contacts an opposite wall of the femoral tunnel. After location of the graft loop in the femoral tunnel, a guide wire is advanced thereunder from the transverse tunnel (FIG. 11). The suspension device is passed along the guide wire after the guide wire is advanced under the graft loop. The head of the device is advanced as far as a distal head of a recess (channel opposite to transverse channel) formed in the opposite wall of the femoral tunnel. The graft is urged against the opposite wall as the head is advanced into the recess.

Chervitz et al. disclose the claimed method except for the transverse tunnel terminating in an opposite wall and with the graft loop being compressed between and abutment surface and the opposite wall; rather Chervitz shows a tunnel that accommodates a flexible guide wire.

Clark et al. disclose a traditional guide wire, ref. #18, which does not require the transverse tunnel to exit the femur, thus, Clark et al. disclose the transverse tunnel terminating within the femur (FIG. 13), i.e. an enclosed recess, for delivering the guide

Art Unit: 3733

wire and cross pin under the graft loop. Moreover, Clark et al. disclose that the graft loop is compressed between an abutment surface and the wall in order to secure the graft in the tunnel (col. 4, lines 29-31, and FIG.S. 6-7), i.e. embedded.

It would have further been an obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Chervitz et al. with the transverse tunnel terminating within the femur and the graft loop being compressed in view of Clark et al. for delivering the guide wire and cross pin under the graft loop and secure the graft in the tunnel.

Response to Arguments

Applicant's arguments filed 12/04/2008 have been fully considered but they are not persuasive.

Applicant argues that combination of Chervitz and Clark does not show "forming an enclosed recess in an opposite wall of the femoral tunnel, and embedding the nose of a transverse suspension device into that enclosed recess." The examiner respectfully disagrees. Clark et al. disclose a traditional guide wire, ref. #18, which does not require the transverse tunnel to exit the femur, thus, Clark et al. disclose the transverse tunnel terminating within the femur (FIG. 13) for delivering the guide wire and cross pin under the graft loop, which can be considered an enclosed recess. Moreover, Clark et al. disclose that the graft loop is compressed between an abutment surface and the wall in order to secure the graft in the tunnel (col. 4, lines 29-31, and FIG.S. 6-7), thus, the

Art Unit: 3733

nose of the suspension device can be considered to be embedded in the enclosed recess.

Regarding claim 21 and 29, Applicant argues that the combination of Howell and Chervitz does not disclose “forming an enclosed recess in an opposite wall of the femoral tunnel, and embedding the nose of a transverse suspension device into that enclosed recess.” The examiner respectfully disagrees. Under the broadest reasonable interpretation of the terms “enclosed” and “embedded,” the prior art combination meets the amended claims. “Enclose” can be taken to mean closed in, included within, or confined. “Embedded” can be taken to mean enclosed firmly by a surrounding mass. The combination of Howell and Chervitz clearly meets these limitations.

It is further noted that merely repeating claim terminology without providing any further explanation or arguments as to how the claim amendments distinguish the invention from the cited art is not considered a sufficient response.

The rejections are deemed proper.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARY HOFFMAN whose telephone number is (571)272-5566. The examiner can normally be reached on Monday-Thursday 10:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone

Art Unit: 3733

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. H./

Examiner, Art Unit 3733

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3734